

U.S.S.N. 09/665,303
Filed: September 19, 2000
AMENDMENT AND
RESPONSE TO OFFICE ACTION

Remarks

Upon entry of the foregoing amendment, claims 57-110 are pending in the application.

Claims 57-78, 82-84, 89, 90, 95, 96, and 104 have been deemed withdrawn.

Allowable Subject Matter

Applicants thank the Examiner for the indication that claims 91-94, 99-103, and 105 are directed to allowable subject matter. Claims 91 and 99 are now amended into independent form, and thus claims 91-94, 99-103, and 105 should be allowed.

Amendments to the Claims

Claim 79 has been amended to specify that the medical device is *implantable inside a patient*. Support for this amendment is found at least at page 23, lines 17-21, and original claim 17. Claim 108 has been amended to specify that release of the molecules from each reservoir is passively controlled by *disintegration* of the reservoir cap.

Rejection Under 35 U.S.C. § 102

Claims 79-81, 85-88, 97, 98, and 106-110 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,380,272 to Gross (hereinafter "Gross"). The rejection is respectfully traversed as applied to the claims as amended.

Gross discloses a drug applicator device for administering a drug to a patient through the patient's skin using iontophoresis. The applicator device is adapted to be placed against the outer surface of a patient's skin, and then the device is activated to generate an electrical flux to drive ionic drugs through the skin (Cols. 1-3).

Gross fails, however, to disclose or remotely suggest a medical device that is implantable into a patient, as required by Applicants' claim 79. Gross's device remains located outside of the

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body during use. The device and its reservoirs are never *in vivo*. Hence, the drug molecules in Gross are not *released* from a position *in vivo*, even though the drug molecules subsequently are transported into the body. Applicants' claim 79 requires that the device be implanted *into* the body of a patient, and Gross clearly fails to disclose this limitation. In fact, Gross *teaches away* from drug delivery devices that are implantable or otherwise invasive into the body of the patient. For instance, Gross teaches that "transcutaneous delivery...offers the possibility of the continuous and measured delivery of drugs to the body *without the complication of and inconveniences of intravenous delivery.*" (Col. 1, Lines 35-38). Surgical implantation is far more invasive than an intravenous injection. Therefore, Applicants' claim 79 and all claims dependent thereon are clearly novel and patentable over Gross.

Gross also fails to disclose or suggest a drug delivery device wherein release of the molecules from each reservoir is passively controlled by disintegration of the polymeric reservoir cap, as required by Applicants' claim 108. Gross teaches only an active device; there is no teaching of *passive* controlled release. Furthermore, Gross does not disclose any reservoir cap structure that *disintegrates* to control the release. Therefore, Applicants' claim 108 and all claims dependent thereon are clearly novel and patentable over Gross.

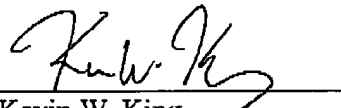
Conclusions

In view of the above amendments and remarks, Applicants respectfully submit that the claims are in condition for allowance. Prompt allowance of the pending claims is respectfully solicited.

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The undersigned respectfully invites the Examiner to contact him by telephone if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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